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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **KILIBWA**

Serial No.: **08/796,305**

Group Art Unit: **1761**

Filed: **February 7, 1997**

Examiner: **Tran Lien, T.**

For: **POLYEXTROSE AS ANTI-STALING AGENT**

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

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Sir:

RULE 132 DECLARATION

I, Caroline Garman, hereby declare:

1. I, Caroline Garman, have been the Application Manager for Bakery at Danisco Sweeteners since 1995. I am a technical expert in baked good applications including the usage of Litesse® polydextrose in a variety of baked goods. A brief biographical listing of my career experience and professional achievements is attached as exhibit A.
2. I have fully reviewed U.S. Patent No. 4,678,672 to Dartey et al ("Dartey" hereafter). Dartey teaches a method of producing crackers with a reduced calorie content by including a significant amount of polydextrose in the product. In Dartey, the method achieves at least a 25% calorie reduction (col. 6, lines 45-47) by incorporating a sufficient amount of polydextrose and/or cellulosic bulking agent as a flour replacement in order to achieve the desired calorie reduction. Dartey further states that a replacement of 20% (w/w) of the cracker recipe composition with a non-digestible, zero-calorie cellulosic flour substitute can only achieve a calorie reduction of about 10% (col. 3, lines 53-59). Therefore, based on Dartey's teachings, a typical recipe with the maximum amount of 10% of cellulosic bulking agent added, will exhibit only a 5% calorie reduction.

3. In terms of calorie contribution, polydextrose is the same as the cellulosic flour substitute because they both contribute essentially zero calories to the cracker product. Thus, addition of less than 10% polydextrose in the cracker recipe composition of Dartey, with concurrent use of the maximum amount of cellulosic flour substitute (10% w/w), would achieve a calorie reduction of only about 10%. Therefore, since Dartey requires at least a 25% calorie reduction (col. 6, lines 45-47), Dartey clearly envisions recipes, which contain significantly more than 10% polydextrose (w/w) based on the total dough composition.
4. Since the flour content of such dough compositions is significantly less than 100%, this means that to achieve its desired 25% calorie reduction, Dartey must use far more than 10% polydextrose w/w based on the flour weight, expressed in terms of the claims of the present application. For example, with a flour content of 68.2% as in the recipe given below in paragraph 6 of this declaration, 10% by weight of polydextrose, based on the weight of the dough composition, equates to at least 14.66% by weight of polydextrose, based on the flour weight of the composition.
5. The crackers produced using the method disclosed in Dartey are required to have a calorie content of 2.9-3.3 kcal/gram (col. 8, lines 15-17). In contrast, a typical cracker has a calorie content of about 4.4 kcal/gram. Dartey uses the term "cal/gram" in the patent application but he actually means "kcal/gram." The calorie content of a food composition will be in the range of a few kcal/gram instead of a few cal/gram and thus this is an obvious error to a skilled person.
6. To further illustrate the fact that Dartey would actually teach a skilled person in art away from the present invention, a typical cracker recipe which meets all the requirements of the present invention is illustrated below. A typical recipe of the present invention contains:

68.2% by weight of flour;
6.8% by weight of polydextrose;

10% by weight of a combination of one or more of a fat, shortening or an emulsifier, with the emulsifier not exceeding 5% by weight;
10% by weight of cellulosic bulking agent or flour substitute; and
5% by weight of a leavening agent,

based on the total weight of the dough.

7. By using common simulation software as described in detail below, a person skilled in art can determine that crackers produced from the above dough composition would have a caloric content of about 3.61-3.68 kcal/gram. The above recipe produces a cracker having a calorie content far higher than the cracker desired by Dartey having only 2.9-3.3 kcal/gram. Therefore, the above recipe, even though it falls within the broad ranges of Dartey relied upon by the U.S. Patent Examiner and disclosed at col. 6, line 58 to col. 7, line 10 of Dartey, is not envisioned by Dartey's teachings since the calorie content of the final cracker is far above the range of 2.9-3.3 kcal/gram required by Dartey at col. 8, lines 15-17.
8. From this it is clear that the Dartey reference does not teach a skilled person to make any composition as described by the broad ranges of ingredients given at col. 6, line 58 to col. 7, line 10 of Dartey. Instead, Dartey teaches a skilled person to make a subset of those compositions, namely, only those compositions, which produce a cracker having a calorie content of 2.9-3.3 kcal/gram.
9. To further support this conclusion, crackers produced from dough compositions that fit the above criterion but using different types of flour were simulated using the commercial recipe evaluation software "Recipe Developer Version 1.4.008 Beta ©Hamilton Grant Software Limited 2001." The software calculates the calorie contribution of each ingredient based on known parameters such as the calorie content and typical moisture content of each ingredient.
10. Two different crackers were simulated with two identical dough compositions using different types of flour. Each cracker was simulated using the recipe of paragraph 6 of this Declaration

at 100g scale. Each simulation of the recipe used Litesse II® polydextrose, Sweetex® high ratio shortening, Solka Floc 300® cellulosic bulking agent, and sodium bicarbonate leavening agent.

11. The first cracker was simulated using white breadmaking flour as the flour in the dough composition described above. The dough composition eventually produces 100 g of the cracker having a total calorie content of 360.855 kcal, which results in the first cracker having a calorie content of 3.61 kcal/gram, significantly outside the range of 2.9-3.3 kcal/gram required by Dartey.
12. The second cracker was simulated using hard spring wheat flour as the flour in the dough composition described above. The dough composition eventually produces 100 g of the cracker having a total calorie content of 367.886 kcal, which results in the second cracker having a calorie content of 3.68 kcal/gram.
13. Every gram of the white breadmaking flour contains 3.58 kcal/gram. To achieve a cracker with a calorie content less than 3.3 kcal/gram based on the recipe exemplified in this declaration using the teachings of Dartey, the polydextrose content in the dough composition has to be increased by an additional 13.8 grams to a total of 20.6 grams while the flour content must be reduced by the same amount. This would require the polydextrose content in this dough composition be 37.9% (w/w) of the flour weight, far outside the range of less than 10% (w/w) of polydextrose based on flour weight claimed in the present invention. This dramatic increase in polydextrose would also impair the dough's processability, which renders the dough recipe almost useless. Therefore, a skilled person in reading Dartey would intentionally avoid the above-described recipe of the present invention because the calorie content of the resulting crackers would be outside the range of 2.9-3.3 kcal/gram required by Dartey.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that the statements were made with the knowledge that willful false statements and the like made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: 16/12/01

Caroline Garman
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